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July 13, 2026

Russell Vought
Director
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

Re: Docket OMB-2026-0034: Regulation for Federal Financial Assistance

Dear Mr. Vought:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Office of Management and Budget (OMB) for the opportunity to provide input to the Regulation of Federal Financial Assistance proposed rule. APIC is a nonprofit, multidisciplinary organization representing 15,000 infection preventionists (IPs) whose mission is to create a safer world through the prevention of infection.

The daily work of infection prevention depends on the integrity, continuity, and independence of federally funded research. Programs and guidance that infection preventionists often rely on — including CDC- and AHRQ-funded studies on device-associated infection prevention, NIH-funded microbiology and antimicrobial-resistance research, and multi-site cluster-randomized trials conducted through federally supported research networks — have directly shaped the clinical practices that protect patients in healthcare facilities nationwide. The value of effective infection prevention and control programs is made evident by CMS' value-based purchasing (VBP) programs, which incentivize healthcare organizations to improve patient outcomes and provide high quality care at a lower cost to Medicare and Medicaid. Many of the CMS-measured outcomes are healthcare-associated infections (HAIs) which have been significantly reduced over the past several decades in US hospitals because of federally funded research, saving American lives and Federal tax dollars. Research is also critical to preventing other significant threats to US security and public health, such as the rise in antimicrobial resistance and risk of outbreaks from emerging infectious diseases. These threats continue to evolve as healthcare becomes more complex and the global population more mobile. The scientific body of work that drives prevention and control activities must continue to be agile and timely to cope with these threats. Likewise, grant-funded public health initiatives drive community level preparedness and provide support and expertise to healthcare facilities.

We recognize the legitimate goals of this proposed rule states: improving transparency, preventing fraud and waste, and reducing unnecessary administrative burden on recipients. We support those goals and do not object to the rule's provisions addressing subaward reporting, payment verification, or reduction of duplicative paperwork. However, several specific provisions raise serious concerns about the future objectivity, continuity, and international competitiveness of federally funded research, including research that underpins patient safety and infection prevention practice. We respectfully urge OMB to reconsider or substantially narrow the provisions identified below before finalizing this rule.

Part 200 Subpart A: Definitions
Part 200 Subpart B: General Provisions

While APIC supports increasing transparency, oversight, and accountability, as well as decreasing burden, we have concerns that several of the items included in the subparts A and B may increase burden through decreased flexibility. Maintaining the term "guidance" is important because changing it to "regulation" could inadvertently reduce the discretion and flexibility necessary to implement the grant process across diverse situations and recipients.

Section 200.101 Applicability
While OMB states that elimination of fixed amount awards will increase transparency and oversight, a consequence of this proposal would be to increase administrative burden and reduce flexibility in managing subawards. Conditions already exist for managing fixed amount awards including prior approval requirements and periodic reports.

Part 200 Subpart C: Pre-Federal Award Requirements and Contents of Federal Awards

The goal of Infection Prevention and Control (IPC) is to keep people healthy and free from infections. The IPC field relies on the latest research and evidence to formulate guidelines that promote public health and patient safety within healthcare institutions. The proposed rule creates instability within the scientific research community and will impact the funding of research that will advance the field, such as life-saving prevention and treatment therapeutics, disease transmission and disease transmission prevention, and the health impacts on all populations. The federal government should use objective scientific evidence to identify strategic priorities that advance the health of the country.

Several proposals in Subpart C (200.201, 200.202, 200.205, 200.206) will create an unmanageable environment by introducing uncertainty into the award issuance process by advancing perpetual updates to fixed amount grants.

Section 200.202 Program Planning and Design

Section 200.202(c)

APIC supports the principle that federal funds should be used for public purposes authorized by the underlying statute. However, the proposed text and accompanying example (restricting funds used to "subsidize political activities or initiatives unrelated to authorized public purposes") is subjective, broad enough to be applied inconsistently, and could be used to disqualify legitimate scientific inquiry into topics that are politically sensitive but scientifically and clinically important — for example, research into disparities in healthcare-associated infection rates across different patient populations, which is directly relevant to effective infection prevention but touches on subject matter that could be mischaracterized as ideological. We ask OMB to clarify that this provision is not intended to restrict scientifically grounded research design choices, including analysis of demographic or population-level variables where scientifically warranted.

Section 200.202(e)

Infectious disease and antimicrobial resistance research are inherently international: pathogens cross borders, and some of the most consequential advances in infection prevention have depended on international consortia, collaboration with the World Health Organization, and multinational surveillance networks. A blanket eligibility restriction on international elements of research and development awards — evaluated case-by-case for alignment with "the national interest," without defined criteria — risks cutting off collaborations that materially strengthen U.S. public health security rather than threaten it. We urge OMB to replace the current open-ended standard with specific, narrowly tailored security criteria developed in consultation with the scientific community, and to provide a transparent waiver process for collaborations that support U.S. public health, biosecurity, or pandemic preparedness objectives.

Section 200.205: Federal Agency Merit Review of Proposals

The proposed revision requires that political appointees conduct a new pre-issuance review of proposals selected for funding, explicitly to ensure alignment with "the President's policy priorities," while clarifying that scientific peer review "remains advisory and does not replace agency discretion." Independent, investigator-driven peer review — evaluating proposals on scientific rigor, methodology, and reproducibility — has been the cornerstone of federal research funding integrity for decades, under administrations of both parties. Subordinating that review to a political alignment test, applied by political appointees rather than subject-matter experts, introduces the risk that funding decisions will track the policy preferences of whichever administration is in office rather than the scientific merit of the proposal. This risk applies regardless of which party holds the White House, and this same concern would be raised if the political alignment criteria pointed in a different ideological direction. APIC urges OMB to preserve peer review as the primary and binding basis for funding decisions, to ensure that federally funded research is addressing gaps in scientific knowledge and addressing the needs of the public, and to remove or substantially narrow the requirement that awards demonstrate alignment with the priorities of the current administration as a distinct and controlling criterion.

Section 200.206(b)(2): Federal Agency Review of Risk Posed by Applicants

The proposed addition allowing agencies to consider an applicant's "affiliations with organizations engaged in activities that violate Federal law, undermine public safety or national security, or advocate for the overthrow of the United States Government" is not defined with sufficient precision to be applied consistently or fairly. As written, this standard could be interpreted to penalize legitimate academic, professional, or advocacy affiliations that have no bearing on a researcher's scientific competence or the integrity of the proposed work. Membership in academic or professional organizations is extremely valuable to help build a network of scientists to strengthen rigor and robustness of scientific findings and professional expectations. We recommend that OMB either remove this provision or replace it with narrowly tailored, objectively verifiable criteria, paired with a clear appeals process for applicants who believe they have been unfairly flagged.

Part 200 Subpart D: Post Federal Award Requirements

Infection prevention and healthcare-associated infection research require stable, multi-year funding, uninterrupted surveillance, and the ability to objectively examine infection outcomes across diverse patient populations. Proposed Subpart D provisions regarding discretionary termination, suspension, and national policy requirements may unintentionally discourage critical research necessary to prevent healthcare-associated infections, antimicrobial resistance, emerging infectious diseases, and future

public health threats. We urge OMB to clarify that objective epidemiologic, infection prevention, patient safety, quality improvement, and public health surveillance activities remain protected and should not be adversely affected by policy-based termination or compliance concerns absent fraud, misconduct, or material noncompliance.

Section 200.300 Statutory and National Policy Requirements

Infection prevention and public health research must also retain the ability to appropriately study and analyze factors such as sex, race, ethnicity, nationality, and other population characteristics when scientifically justified. These variables can influence disease prevalence, infection risk, treatment effectiveness, healthcare outcomes, and the implementation of prevention strategies. Limiting the ability of researchers to examine these factors may reduce the applicability of research findings, hinder identification of at-risk populations, and ultimately compromise efforts to provide safe, evidence-based care for all healthcare recipients.

Section 200.303: Internal Controls

We are concerned that removal of explicit reference to widely recognized internal control frameworks, such as the GAO's "Standards for Internal Control in the Federal Government" or the "Internal Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), may create uncertainty regarding the minimum expectations for an effective internal control environment. Although the GAO resides within the Legislative Branch of the U.S. government, its mission is to provide non-partisan and non-ideological audit, evaluative, and investigative analyses to all branches of the U.S. government as well as external partners. While GAO and COSO do not operate under the Executive Branch, these organizations have widely recognized internal control frameworks, which the Executive Branch does not currently have. Recipients and subrecipients of government grants need clear guidance on how compliance with §200.303 will be assessed in the absence of established reference frameworks. Without defined standards, organizations may face challenges implementing controls consistently, and auditors may apply subjective interpretations of what constitutes sufficient internal controls.

Section 200.340: Termination and Suspension

Scientific research requires stability, continuity, and protection from arbitrary interruption. Research studies are designed to answer specific hypotheses through rigorous, pre-approved methodologies that often involve human participants, years of data collection, and substantial public investment. The proposed clarification would allow agencies to terminate discretionary awards mid-course when a project is found inconsistent with agency priorities that may shift over time and are not tied to statute. Much of the research that has meaningfully reduced healthcare-associated infections — including large, multi-year, multi-site cluster-randomized trials — requires years of stable funding to reach a valid, generalizable conclusion. Terminating a research award mid-study because priorities have shifted or because another investigator, institution, or topic is later viewed as more desirable—when there are no concerns about scientific merit, compliance, safety, or performance—risks undermining the integrity of the scientific process. Such actions may leave important clinical and public health questions unanswered, waste taxpayer investments already made, diminish the contributions of research participants, and delay discoveries that could improve patient outcomes. Scientific progress depends on

objective scientific criteria, not changing preferences or subjective reassessments after research is already underway. We recommend that OMB limit discretionary termination authority to circumstances involving documented noncompliance, fraud, or failure to perform, rather than shifting policy priorities alone.

Part 200 Subpart E: Cost Principles

As infection preventionists, we are not typically the direct recipients of grant funding, but the knowledge that is generated from federally funded primary research is critical to our work. Effective infection prevention and control programs implement care "bundles" in healthcare settings which consist of several practices proven through primary research to improve patient safety and enhance the quality of care provided to patients. These practices are identified through literature review, meta-analyses, and other types of research which rely on a robust data set available in scientific journals and at professional conferences. Several provisions as drafted are overly broad, operationally impractical, and risk undermining core functions of how federally funded scientific evidence is generated, translated, and implemented in healthcare settings.

The US has long been at the forefront of prevention and readiness research and yet the activities most directly responsible for timely dissemination of best practices that reduce healthcare-associated infections are placed at risk of being treated as unallowable costs under the proposed framework. The proposed changes may also be misaligned with the OMB overarching goal to improve transparency and accountability by significantly hampering the dissemination of important findings and expertise funded by Federal grants. We strongly feel that the scientific process and rigor of research into improving outcomes in US healthcare facilities and in communities will be seriously weakened by the proposed changes and urge OMB to reconsider.

Section 200.432: Conferences

The proposed requirement that all conference attendance be explicitly approved by the awarding agency and incorporated into the terms and conditions of the award is operationally rigid, administratively burdensome, and misaligned with the pace of infectious disease science.

For public health and healthcare research, conferences play a particularly important role in the rapid dissemination of emerging evidence, best practices, and lessons learned that can directly influence patient safety, infection prevention, outbreak response, antimicrobial resistance trends, and healthcare quality improvement efforts. Limiting participation in these scientific exchanges could impede the timely translation of federally funded research into improvements in healthcare delivery and public health outcomes.

A blanket pre-approval requirement introduces unnecessary administrative delay and reduces the agility of IPC and public health programs to respond to evolving infectious threats. Requiring conference attendance to be specifically identified and approved at the time of issuance is not practical as important opportunities to present findings often arise after an award is issued and cannot reasonably be anticipated during proposal development.

A more appropriate approach would preserve allowability when conference participation is clearly aligned with award objectives and supported by internal documentation. At a minimum, we recommend maintaining flexibility for recipients to seek post-award approval when conference participation arises that could not reasonably have been anticipated at the time of award issuance.

Section 200.450: Lobbying

The proposed expansion of lobbying restrictions into "issue advocacy" and public messaging is overly broad, insufficiently defined, and presents a substantial risk of chilling legitimate scientific and public health communication.

The language prohibiting messaging that "promotes or opposes a particular social, political, or public policy position" or that "influences public attitudes" is not operationally distinguishable from standard infection prevention practice. Core infection prevention activities routinely involve influencing clinical behavior and institutional practice based on scientific evidence.

Surveillance reporting, outbreak communication, implementation of prevention bundles, and dissemination of guideline-based recommendations necessarily shape behavior and organizational decision-making. Under the proposed framing, these activities could be mischaracterized as impermissible "issue advocacy," creating significant compliance uncertainty and risk aversion in federally funded programs.

In addition, restrictions on communication with state or local public health entities threaten to impair coordinated outbreak response and action, which depend on rapid, bidirectional exchange of epidemiologic and operational information.

We recommend that OMB clearly delineate scientific communication, technical assistance, and evidence dissemination from political advocacy to avoid unintended suppression of legitimate infection prevention activities.

Section 200.461: Publication and Printing Costs

The proposed restriction on publication costs to only statutorily required or case-by-case pre-approved activities represents a significant departure from established norms of federally funded scientific research which relies on Open Access to ensure that funded projects are available to all Americans. Restriction is likely to have adverse consequences for transparency and effectiveness of findings.

Publication is not a discretionary or ancillary expense in scientific work; it is the primary mechanism through which federally funded research is validated, scrutinized, and translated into practice. In infection prevention, timely publication of outbreak investigations, intervention evaluations, and surveillance analyses are essential for replication, scale-up, and national learning.

The proposed policy would introduce structural barriers to dissemination, delay scientific communication, and reduce the return on investment of federal research funding. We recommend that publication costs remain allowable when directly resulting from funded activities and when consistent with agency public access and dissemination policies.

Subpart F: Audit Requirements

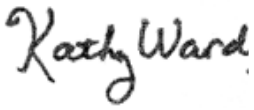
Section 200.503: Relation to Other Audit requirements

Auditing is a necessary control to assure compliance, accountability, and safety. While APIC appreciates the intent to reduce burden, we are concerned that the weakened authority to audit only as required by statute will result in unidentified risks and safety concerns. We oppose removing discretionary audit authority as well as deletion of the word annual before compliance supplement in §200.513(c)(4).

Conclusion

The leadership of the United States in biomedical and public health research has depended on a durable, bipartisan norm: that federal funding decisions are made on the basis of scientific merit, evaluated by qualified experts, insulated from short-term political direction. APIC shares OMB's stated interest in eliminating waste, fraud, and genuine misuse of taxpayer funds, and we do not raise these concerns to defend any specific program, institution, or ideology. Our concern is narrower and nonpartisan: that specific mechanisms in this proposed rule would allow funding decisions, once made, to be reopened or reversed based on shifting political criteria rather than the scientific and programmatic standards on which the original award was based. If finalized as written, we are concerned this could produce lasting harm to American research capacity, discourage ambitious long-term studies, and weaken the pipeline of evidence that directly protects patients in healthcare facilities. APIC respectfully requests that OMB revise the provisions identified above before finalizing this rule, and we appreciate the opportunity to comment.

Sincerely,



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